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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/031,180 | 08/05/2002 | Alistair Dixon | A0000096-01-SMH | 2579 |

7590 06/29/2005

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| EXAMINER |
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HUI, SAN MING R

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/031,180 | DIXON ET AL. | |
| | Examiner | Art Unit | |
| | San-ming Hui | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-25,52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-25,52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed April 15, 2005 have been entered. The cancellation of claims 5, 26-51, and 54-55 is acknowledged.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed April 15, 2005.

The outstanding rejection under 35 USC 103 of claim 5 is withdrawn in view of the cancellation of the claim.

Claims 1-4, 6-25, 52, and 53 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-25 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01426 ('426).

'426 teaches the elected specie ***N-cyclopropylmethoxy-3,4,5-trifluoro-2-(4-iodo-2-methyl-phenylamino)-benzamide*** as MEK inhibitors that is useful in treating proliferative diseases such as cancer (See page Compound example 79, also the abstract).

'426 does not expressly teach the elected specie as useful in treating chronic pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected specie in a method of treating chronic pain.

One of ordinary skill in the art would have been motivated to employ the elected specie in a method of treating chronic pain since cancer is always associated with chronic pain. Therefore, employing the elected specie in a method of treating cancer in cancer patients before or after surgical removal of the cancer and thereby providing chronic pain relief would be reasonably expected to be effective.

Furthermore, neuroma is a brain tumor that affecting the auditory nerve in the head. Therefore, the method of employing the elected specie to treat such tumor (proliferative disease) would be reasonably expected to be useful.

Claims 1-4, 6-25 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/01421 ('421).

'421 teaches a 4-iodo phenylamino benzamide compounds, including the elected specie, as MEK inhibitors and as useful to treat diabetes, proliferative disorders such as cancer, and inflammation (See the abstract, claims 26, 31, 33).

'426 does not expressly teach the elected specie as useful in treating chronic pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected specie in a method of treating chronic pain.

One of ordinary skill in the art would have been motivated to employ the elected specie in a method of treating chronic pain since cancer is always associated with

chronic pain. Therefore, employing the elected specie in a method of treating cancer in cancer patients before or after surgical removal of the cancer and thereby providing chronic pain relief would be reasonably expected to be effective.

Response to Arguments

Applicant's arguments filed April 15, 2005 averring pain as not always associated with cancer have been fully considered but they are not persuasive. As taught in the prior arts provided by the applicant, pain is present in majority of cancer patients. Therefore, the basis of the rejection should be remain since it would be obvious to one of ordinary skill in the art would employ the herein claimed compounds for treating cancer-associated chronic pain. Examiner notes that the instant claims are so broad that they encompass the treatment of chronic pain caused or associated by any conditions. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to employ the herein claimed compounds to treat chronic pain that is associated with cancer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
Art Unit 1617